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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,196	04/17/2006	Jong Soo Woo	Q94466	8697

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EXAMINER	
TATE, CHRISTOPHER ROBIN	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,196	WOO ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0406 & 0706*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide an adequate written description which adequately delineates the metes and bounds of the instantly claimed phrases "silybin or a derivative thereof" and "extract containing silybin or derivatives thereof" (see, e.g., claims 1 and 4). That is, other that stating within the instant specification that derivatives of silybin include silycristin, silydiamin, and isosilybin (see, e.g., first full paragraph on page 3 of the instant specification), the instant specification fails to provide an adequate written description as to the manner and process of making and using such active derivatives, especially given the enormous permutation of potential compounds such silybin derivatives read upon (please note that a derivative of silybin could be anything from one of numerous small molecular fragments of silybin to a singular atom thereof, as well as larger and/or complexed molecules that happen to contain a partial silybin and/or silybin-like core structure therein).

Accordingly, the phrases "silybin or a derivative thereof" and "extract containing silybin or derivatives thereof" are deemed to lack adequate written description.

It is suggested that the phrases "or derivative thereof" and "or derivatives thereof" be omitted from the claim language wherever they appear to overcome the above rejection.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an oral microemulsion composition for treating a liver disease comprising silybin or an extract of *Carduus marianus* containing silybin, in combination with the other recited ingredients, does not reasonably provide enablement for an oral microemulsion composition for treating a liver disease comprising a derivative of silybin or an extract of *Carduus marianus* whereby the extract is only defined as containing derivatives of silybin, in combination with the other recited ingredients . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants have reasonably demonstrated that an oral microemulsion composition comprising silybin and/or an extract of *Carduus marianus* containing silybin (i.e., "*Carduus marianus* (as silybin)" - as shown in the instant Examples including Examples 1-5), in combination with biphenyldimethyldicarboxylate (BDD), as active ingredients; a co-surfactant, a surfactant, and an oil is useful *in vivo* as a therapeutic agent for treating one of various liver diseases. However, the claims encompass the use of any and all derivatives of silybin and/or an extract of *Carduus marianus* whereby the extract is only defined as containing derivatives of silybin, in combination with the other recited ingredients for such an *in vivo* purpose, which is

clearly beyond the scope of the instantly demonstrated invention. Please note that inventions targeted for *in vivo* therapy (such as for treating one or more liver diseases - as instantly claimed/disclosed) bear a heavy responsibility to provide supporting evidence in terms of what the instant claim language encompasses by the phrases "silybin or derivative thereof" and "extract containing silybin or derivatives thereof" because of the unpredictability in biological responses to such therapeutic treatment.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to successfully treat a liver disease *in vivo* via administering an oral microemulsion composition comprising a derivative of silybin or an extract of *Carduus marianus* whereby the extract is only defined as containing derivatives of silybin, in combination with the other recited ingredients for the reasons fully set forth above.

It is again suggested that the phrases "or derivative thereof" and "or derivatives thereof" be omitted from the claim language wherever they appear to overcome the above rejection.

With respect to the two USC 112, first paragraph rejections, all other claims depend directly or indirectly from rejected claims and are, therefore, also rejected for the reasons set forth above.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 4 are rendered vague and indefinite by the phrases "silybin or derivative thereof" (recited in claims 1 and 4 - line 2 of each) and "extract containing silybin or derivatives thereof" (recited in claim 1 - line 3). Other than the silybin derivative being silycristin, silydiamin, or isosilybin (which is taught by the instant specification as being particular derivatives of silybin -see, e.g., first full paragraph on page 3 of the instant specification), it is unclear what the cited phrases "silybin or derivative thereof" and "extract containing silybin or derivatives thereof" are actually defining. Please note that a derivative of silybin could be anything from one of numerous small molecular fragments of silybin to a singular atom thereof, as well as larger and/or complexed molecules that happen to contain a silybin and/or silybin-like core structure therein. Accordingly, the metes and bounds of what a "derivative" of silybin is actually defining are not clearly nor adequately delineated. Based upon the overall teachings of the instant specification including the instant Examples, it is suggested that the phrases "or derivative thereof" and "or derivatives thereof" be omitted from the claim language wherever they appear to overcome this rejection.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/536,351 in view of Woo et al. (US 6,428,821).

The instant claims and the claims of Appl. No. '351 are both drawn to an oral microemulsion composition comprising BDD, a co-surfactant, a surfactant, and an oil (within overlapping ratio amounts thereof). However, the instantly claimed microemulsion composition (for use in treating a liver disease) further comprises silybin or derivative thereof and/or a *Carduus marianus* extract containing silybin or derivatives thereof, which is not recited within the claim language of Appl. No. '351.

Woo et al. beneficially teach an oral microemulsion composition (for use in treating/protecting the liver) comprising silybin or derivative thereof and/or a *Carduus marianus* extract containing silybin or derivatives thereof, in combination with a co-surfactant, a surfactant, and an oil (within overlapping and/or similar ratios to those instantly claimed as well as those recited within the claim language of the Appl. No. '351) - see entire document.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to further include silybin and/or a *Carduus marianus* extract containing silybin within the instantly claimed microemulsion composition since both are similar oral microemulsion compositions which are useful for treating/protecting the liver.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being obvious over Woo et al. (US 6,428,821) in view of Kim et al. (J. Controlled Release, 2001).

Woo et al. beneficially teach an oral microemulsion composition (for use in treating/protecting the liver) comprising silybin or derivative thereof and/or a *Carduus marianus* extract containing silybin or derivatives thereof, in combination with a co-surfactant, a surfactant, and an oil (within overlapping and/or similar ratios to those instantly claimed), and that such a microemulsion composition provides for better bioavailability and solubility (e.g., improved wetting) - see entire document including Abstract; cols 1-2; Examples; Claims. Woo et al. do not teach the further incorporation of BDD therein.

Kim et al. beneficially teach a microemulsion composition containing BDD which comprises an oil, a surfactant, and a co-surfactant for improving the solubility and bioavailability thereof. Kim further discloses that such a composition is useful for treating liver diseases and/or hepatic injury (see entire document including Abstract, Introduction, and Table 1).
It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to further include BDD within the a microemulsion composition such as that taught by Woo et al. because Woo et al. teach that their composition is useful in treating/protecting the liver and Kim et al. disclose that BDD is useful in treating liver diseases and/or hepatic injury. Conversely, it would have been obvious to further include silybin (or derivative thereof) and/or a *Carduus marianus* extract containing silybin within the a microemulsion composition such as that taught by Kim et al. because Kim et al. teach that their composition is useful in treating liver diseases and/or hepatic injury and Woo et al. teach that silybin or derivative thereof (or a *Carduus marianus* extract comprising silybin) is useful in treating/protecting the liver. Accordingly, one would have a reasonable expectation of success in combining silybin (or derivative thereof or a *Carduus marianus* extract comprising silybin) and BDD within an oral microemulsion composition based upon the beneficial teachings provided by the cited references. The adjustment of particular conventional working conditions (e.g., determining appropriate amounts and/or ratios of such ingredients therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher R. Tate/
Primary Examiner, Art Unit 1655